

# DIN EN ISO 13485:2016-08 (E)

## Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

---

<b>Contents</b>		<b>Page</b>
European foreword.....		4
Foreword.....		6
Introduction.....		7
<b>1</b>	<b>Scope.....</b>	<b>10</b>
<b>2</b>	<b>Normative references.....</b>	<b>10</b>
<b>3</b>	<b>Terms and definitions.....</b>	<b>10</b>
<b>4</b>	<b>Quality management system.....</b>	<b>15</b>
4.1	General requirements.....	15
4.2	Documentation requirements.....	16
4.2.1	General.....	16
4.2.2	Quality manual.....	16
4.2.3	Medical device file.....	16
4.2.4	Control of documents.....	17
4.2.5	Control of records.....	17
<b>5</b>	<b>Management responsibility.....</b>	<b>18</b>
5.1	Management commitment.....	18
5.2	Customer focus.....	18
5.3	Quality policy.....	18
5.4	Planning.....	18
5.4.1	Quality objectives.....	18
5.4.2	Quality management system planning.....	18
5.5	Responsibility, authority and communication.....	19
5.5.1	Responsibility and authority.....	19
5.5.2	Management representative.....	19
5.5.3	Internal communication.....	19
5.6	Management review.....	19
5.6.1	General.....	19
5.6.2	Review input.....	19
5.6.3	Review output.....	20
<b>6</b>	<b>Resource management.....</b>	<b>20</b>
6.1	Provision of resources.....	20
6.2	Human resources.....	20
6.3	Infrastructure.....	21
6.4	Work environment and contamination control.....	21
6.4.1	Work environment.....	21
6.4.2	Contamination control.....	21
<b>7</b>	<b>Product realization.....</b>	<b>21</b>
7.1	Planning of product realization.....	21
7.2	Customer-related processes.....	22
7.2.1	Determination of requirements related to product.....	22
7.2.2	Review of requirements related to product.....	22
7.2.3	Communication.....	23
7.3	Design and development.....	23
7.3.1	General.....	23
7.3.2	Design and development planning.....	23
7.3.3	Design and development inputs.....	23
7.3.4	Design and development outputs.....	24
7.3.5	Design and development review.....	24

7.3.6	Design and development verification.....	24
7.3.7	Design and development validation.....	24
7.3.8	Design and development transfer.....	25
7.3.9	Control of design and development changes.....	25
7.3.10	Design and development files.....	25
7.4	Purchasing.....	26
7.4.1	Purchasing process.....	26
7.4.2	Purchasing information.....	26
7.4.3	Verification of purchased product.....	26
7.5	Production and service provision.....	27
7.5.1	Control of production and service provision.....	27
7.5.2	Cleanliness of product.....	27
7.5.3	Installation activities.....	27
7.5.4	Servicing activities.....	28
7.5.5	Particular requirements for sterile medical devices.....	28
7.5.6	Validation of processes for production and service provision.....	28
7.5.7	Particular requirements for validation of processes for sterilization and sterile barrier systems.....	28
7.5.8	Identification.....	29
7.5.9	Traceability.....	29
7.5.10	Customer property.....	29
7.5.11	Preservation of product.....	29
7.6	Control of monitoring and measuring equipment.....	30
<b>8</b>	<b>Measurement, analysis and improvement.....</b>	<b>31</b>
8.1	General.....	31
8.2	Monitoring and measurement.....	31
8.2.1	Feedback.....	31
8.2.2	Complaint handling.....	31
8.2.3	Reporting to regulatory authorities.....	31
8.2.4	Internal audit.....	31
8.2.5	Monitoring and measurement of processes.....	31
8.2.6	Monitoring and measurement of product.....	31
8.3	Control of nonconforming product.....	33
8.3.1	General.....	33
8.3.2	Actions in response to nonconforming product detected before delivery.....	33
8.3.3	Actions in response to nonconforming product detected after delivery.....	33
8.3.4	Rework.....	33
8.4	Analysis of data.....	33
8.5	Improvement.....	34
8.5.1	General.....	34
8.5.2	Corrective action.....	34
8.5.3	Preventive action.....	34
<b>Annex A (informative) Comparison of content between ISO 13485:2003 and ISO 13485:2016.....</b>		<b>36</b>
<b>Annex B (informative) Correspondence between ISO 13485:2016 and ISO 9001:2015.....</b>		<b>39</b>
<b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC (as amended).....</b>		<b>45</b>
<b>Annex ZB (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC (as amended).....</b>		<b>50</b>
<b>Annex ZC (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC.....</b>		<b>57</b>
<b>Bibliography.....</b>		<b>65</b>